

## Injury Compensation

Injury compensation language is a challenging issue for CDC, particularly on protocols where we collaborate with other institutions who require certain disclaimers that we (and OHRP) interpret as being exculpatory (denying responsibility) and thus unacceptable under 45 CFR 46.116.

Since the large majority of CDC protocols involve no more than minimal risk to subjects, injury compensation language is best left out of most consent forms, since it is only required when a study involves greater than minimal risk. However, many institutions insert injury disclaimers into all of their research study consent forms, regardless of the level of risk. The Human Subjects Activity and CDC IRB chairs have sought guidance from many authorities, including OHRP and the Offices of General Counsel (OGC) at CDC and HHS, on the proper way to address the issue. Based on this ethical and legal advice, the IRBs recently revised the prototype compensation language to comply with federal requirements for greater than minimal risk studies. Please revise your consent form language on compensation for research-related injury to reflect the following themes:

*If you are hurt as a result of being in this study, treatment will/will not be provided by \_\_\_\_\_. CDC/this institution does not normally pay for harm done to you as a result of being in a research study. Thus, you (or your insurer, Medicare, or Medicaid) will have to pay for any care that is needed. However, by signing this consent form and agreeing to be in this study, you are not giving up any of your rights. If you believe that you have been harmed, please contact \_\_\_\_\_ at \_\_\_\_\_ for information on your rights and advice on how to proceed.*